Sterigenics®
A Sotera Health company

February 14, 2019

VIA ELECTRONIC DELIVERY

Honorable Richard J. Durbin
711 Hart Senate Office Building
United States Senate
Washington, D.C. 20510

Honorable Tammy Duckworth
524 Hart Senate Office Building
United State Senate
Washington, DC 20510

Honorable Sean Casten
429 Cannon House Office Building
United States House of Representatives
Washington, D.C. 20515

Honorable Bill Foster
2366 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

Honorable Daniel W. Lipinski
2346 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

Honorable Bradley S. Schneider
1432 Longworth House Office Building
United States House of Representatives
Washington, D.C. 20515

Senators and Representatives:

First, we would like to thank each of you again for taking the time to meet with us on January 29, 2019 and allowing us the opportunity to describe what Sterigenics does and how we safely operate our Willowbrook plant, explain how critical our plant is to the healthcare system, and answer the many questions each of you had.

We received your February 8, 2019 letter inquiring about the CBS Chicago "Investigative Report" concerning our Willowbrook facility and welcome the opportunity to respond to your questions. The CBS "Investigative Report" is filled with misleading and incorrect statements and represents, at best, a misinterpretation, if not an outright distortion of basic facts. We appreciate this opportunity to set the record straight.

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The residents of Willowbrook have been subjected to months of misinformation regarding Sterigenics and its safe use of ethylene oxide ("EO"). The Willowbrook facility operates in compliance with regulations and has a proven record of operating safely, including voluntary actions to consistently improve performance beyond what the regulations require.

The specific questions in the February 8, 2019 letter are set forth below along with the Company's answers.

1. Do you believe there is ever a situation in which it would be appropriate to release biologically significant amounts of EtO directly into the atmosphere without going through the proper pollution control equipment? If yes, please explain. Please provide us with copies of all documents that you rely on to support this position.

Answer:

Sterigenics does not believe it is appropriate to circumvent or bypass pollution control equipment at its Willowbrook facility, and the Company vehemently rejects any suggestion that it has done so or would do so. The Sterigenics Willowbrook facility is committed to controlling EO emissions safely and in compliance with applicable regulatory permits.

The facility has operated pursuant to and in compliance with operating permits issued under the federal Clean Air Act by the Illinois EPA and its Clean Air Act Permit Program ("CAAPP") since the program's inception. Sterigenics takes its regulatory obligations very seriously, and it has not only complied with the requirements of its operating permits, but has gone beyond those requirements by installing emissions control equipment and systems that exceed the USEPA's and Illinois EPA's regulatory standards.

Today, we monitor, capture and control more than 99.9% of the EO used in the sterilization process – ***exceeding regulatory requirements and representing one of the highest control levels in the country for this industry***. The only EO that is released directly to the atmosphere is the remaining .1%, which reflects post-control stack emissions and fugitive emissions estimates.

The CAAPP permit under which Sterigenics operates regulates emissions of ethylene oxide through application of the federal Clean Air Act's National Emissions Standards for Hazardous Air Pollutants ("NESHAP") program. *See* 40 C.F.R. § 63.368 (Ethylene Oxide Emissions Standards for Sterilization Facilities). Neither the USEPA nor the Illinois EPA has promulgated regulations that enforce specific maximum concentrations or levels for EO emissions in the atmosphere. Instead, the NESHAP requires the use and operation of emissions control systems that reduce emissions from the sterilization chambers and aeration rooms to an exacting level of efficiency – elimination of 99% of the EO emissions.[1]

On January 30, 2006, the Illinois EPA issued modified CAAPP Permit No. 95120085 to Sterigenics for the Willowbrook facility and on June 8, 2015, the Illinois EPA renewed CAAPP permit No. 95120085. This permit includes the NESHAP for EO emissions from sterilization facilities. Neither the Sterigenics permit nor the NESHAP requires facilities to control EO emissions from backvent valves. Nonetheless, in June 2018,

[1] The NESHAP also permits an alternative limit for aeration rooms, instead of 99%. Prior testing at Willowbrook has demonstrated compliance with both alternatives.

Sterigenics voluntarily submitted a construction permit application to connect the backvents to the emission control equipment and thereby further reduce the emissions from the Willowbrook facility. On June 26, 2018, the Illinois EPA issued Permit No. 18060020 to duct the emissions of EO from the backvent valves to existing pollution control devices. Once these backvent valves became ducted, they too were subject to NESHAP's 99% control requirement.

We are emitting far below the levels allowed in the CAAPP permit and the NESHAP at our Willowbrook facility. In addition, Sterigenics reports 100% of its annual estimated emissions of EO in regulatory submissions, accounting for releases through the emission control system, as well as any fugitive emissions that are not captured by that system. Both types of emissions are expressly contemplated by and allowed pursuant to the operating permits issued by the Illinois EPA. The permits issued to Sterigenics by the Illinois EPA are available on its website, at the link here. The regulatory reports regarding these emissions are publicly available here and at the bottom of the page here.

During its webinar on February 5, 2019 to discuss recent air sample results in Willowbrook, the USEPA stated that "it remains premature to draw conclusions about long-term health risks" from EO emissions from the Sterigenics facility. Further, the EPA indicated that amounts of EO recently being measured are "extremely low levels in the atmosphere…part per billion and part per trillion numbers and it doesn't take very much of this material or any material to cause those kinds of levels in the air."

Finally, while USEPA's work continues, its most recent sampling shows average EO levels in residential areas in Willowbrook that are in line with general background levels of EO across the Chicago area and other parts of the country.

2. Do you believe there is ever a situation in which it would be appropriate to dump ethylene glycol into drainage facilities instead of its proper collection process? If yes, please explain.

Answer:

Sterigenics believes that disposal of ethylene glycol always should be done properly and has not illegally "dumped" ethylene glycol into drainage facilities or public sewer systems in violation of any applicable regulations and any accusations to the contrary are simply false.

According to current DuPage County wastewater rules, it is permissible to discharge treated ethylene glycol to the sanitary sewer system so long as the discharge is coordinated with the local sewer district and the glycol is within a certain pH range. *See* DuPage County Code, Chapter 36. These regulations have been in effect for decades. Prior to the purchase of the Willowbrook facility in 1999 by Sterigenics' predecessor, it is our understanding that ethylene glycol periodically was disposed of through the sanitary sewer system in a manner consistent with these regulations. We understand that the local sanitary sewer district was notified of these authorized discharges, and the Willowbrook facility complied with local ordinances regarding them. Currently, Sterigenics has chosen a recycling option whereby the ethylene glycol is sold to a manufacturer as a byproduct. This recycling avoids the need to burden the sewer treatment plant with additional waste.

Sterigenics did experience an accidental release of ethylene glycol in 2013 and one very minor one in late 2018. The 2013 release was cleaned up and the Company obtained a No Further Remediation letter for all affected property. The same process is ongoing now for the minor 2018 release. Finally, we note that recent testing by the Illinois EPA in late 2018 found no evidence of EO or ethylene glycol in local water wells, confirming that the Willowbrook facility has had no impact on local well water.

3. Do you maintain a record of monitor alarm occurrences from EtO at the facility, and does an EtO alarm alert have to be reported to federal or state authorities? How many times have these monitors been triggered since 1993? If so, provide us with copies of these records from 1993 to present day.

a. Does an EtO alarm alert have to be reported to federal or state authorities? If so, please provide us with copies of all documents submitted in connection with those reports from 1993 to present day.

b. **How many times have these monitors been triggered since 1993? Please provide us with a complete list of the exact dates on which the monitors were triggered.**

Answer:

Our voluntary monitoring systems were put into place to provide real-time alerts to our employees of EO levels. This question implies that alarms being "triggered" is an indication of problematic EO exposure issues inside the Willowbrook facility, and that is not necessarily correct.

We have in effect three internal monitoring systems, all of which are designed for employee safety and monitor air within the facility. The three systems are a Gas Chromatography ("GC") monitoring system, a Lower Explosive Level ("LEL") monitoring system, and a personal monitoring (commonly referred to as a "badge") system. The only regulatorily-required system is the personal monitoring system, which is required by OSHA. Our GC and LEL monitoring programs are not required by any regulatory authority, exceed OSHA requirements, and are part of a system that our company voluntarily installed for protection of employee safety inside our building. Accordingly, we are not required to report to any state or federal authorities on these voluntary monitoring systems.

The GC system monitors levels of EO concentrations inside the Willowbrook facility. The system cycles through different monitoring locations (known as "ports") continuously at all hours of every day in order to assist with employee safety. The system is connected to a set of stacked lights (green, yellow, and red) and audible sounds that alert employees to the EO levels in the areas of the corresponding port. Employees use the system to determine when to don personal protective equipment and to inform responsive actions.

The LEL system is designed to measure EO concentrations continuously and to detect significant changes in EO concentration in different areas of the facility that would be an indication of a potential leak of EO. The LEL sensors measure, in percentage terms, the EO concentration compared to the lower flammable or explosive limit of EO. The LEL system conveys information using the same stacked lights and audible alert system that the GC system is connected to.

In 2018, a facility evacuation in Willowbrook 1 or Willowbrook 2 occurred seven times because of high LEL sensor readings. In each case, these were determined to be false alerts caused by faulty LEL sensors. As with any sensor, there can be false readings due to "drift" within the electronic sensors, faulty sensors or circuit boards, or moisture on the sensor. Sterigenics nevertheless requires that its safety procedures are followed until a reading is demonstrated to be false. Again, safety is Sterigenics' paramount concern.

We have 56 total GC and LEL sensors in our Willowbrook 1 facility, and 31 total GC and LEL sensors in our Willowbrook 2 facility. These sensors provide complete facility coverage as well as redundancy.

4. **What is the protocol for employees and facility management when an EtO alarm sounds, whether it be from a personal exposure alarm or a facility-wide alarm? Please provide us with copies of all documents memorializing or interpreting this protocol.**

Answer:

As noted above, our GC and LEL monitoring systems communicate to employees the levels of EO in a given indoor area through colored lights and audible alarms, as well as through panel displays that provide numerical EO readings. Employees are extensively trained on the steps to take in response to these readings. If the EO reading in a particular indoor location is below 1 ppm (the OSHA 8-hour permissible exposure limit ("PEL")), the area monitoring system will display a green light, indicating that it is safe for workers to be in the area. Employees are trained to evaluate whether to use personal protective equipment if EO levels equal or exceed 1 ppm, and are trained to don personal protective equipment if EO levels equal or exceed 3 ppm. Regarding the LEL system, if the LEL sensor reads above 25% of the LEL then the system displays a red flashing light, a constant audible alarm sounds throughout the facility, and a plant evacuation is required.

We are uncertain as to what your question about "personal exposure alarms" is referring. We are unaware of any such alarms. The GC and LEL sensors are stationary, whereas personal monitoring badges are designed to be worn by an individual employee throughout the plant and record the amount of EO to which the employee may be exposed. Personal monitoring is performed by attaching a badge (which is a sampling device) to the employee's clothing to test airborne EO concentrations regardless of where the employee moves in the workplace. Personal monitoring is done on a quarterly basis. Samples are collected for 15 minutes to test short-term exposure and for an 8-hour period to test for average exposures over a time-weighted 8-hour period as required by OSHA. These samples are sent to a third-party laboratory for analysis. *See, e.g.,* U.S. Department of Labor, *Ethylene Oxide (EtO): Understanding OSHA's Exposure Monitoring Requirements*, https://www.osha.gov/Publications/ethylene_oxide.html.

The GC, LEL, and personal monitoring systems all exist to assist our employees in avoiding elevated concentrations of EO and all measure EO levels within the facility, not of emissions outside the facility. We take the safety of our employees very seriously. We would not tolerate any manipulation of these systems in a manner inconsistent with our commitment to employee safety, and we are not aware of any such instances.

5. Please provide us with a detailed description of past incidents at the Sterigenics Willowbrook facility where Sterigenics bypassed pollution control equipment and released EtO directly into the atmosphere.

Answer:

All of the EO emissions from the sterilization chambers, backvents and aeration rooms at the Willowbrook facilities are sent directly to emission control devices. ***Sterigenics does not allow these devices to be bypassed***.

The facility experienced a malfunction of its pollution control systems, which resulted in an uncontrolled release of a small volume of EO, on October 7, 2013. This 12-pound release was reported to the Illinois EPA, and the Company paid a fine and settled the claim by the State of Illinois. There are detailed requirements under federal law for reporting releases of EO releases to federal, state and local authorities, and Sterigenics complies with these laws. ***With the exception of this one incident, Sterigenics has not had a reportable release of EO from its Willowbrook facility since Sterigenics' predecessor purchased the facility in 1999***.

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6. **Please provide us with a detailed explanation on why the alleged actions referenced above in (5) are false or why such actions occurred but were appropriate.**

Answer:

See the response to 5 above.

7. **Please provide us with all documents relating to incidents involving the direct release of EtO into the atmosphere at the Sterigenics Willowbrook facility.**

Answer:

We are unsure what is meant by "direct release" as used in this question. Sterigenics' operating permits allow the release into the atmosphere of a certain small percentage of the EO used annually in sterilization processes. These permitted emissions occur after the EO is captured and processed by the emissions control equipment in accordance with the NESHAP standards and Sterigenics' operating permits, and also through small permitted amounts of fugitive emissions. Both types of emissions are allowed pursuant to the operating permits issued by the Illinois EPA. Permits are available on Illinois EPA's website, available here. Regulatory submissions regarding these emissions are also publicly available at the links provided above in response to Question 1. ***As noted above, with the one exception of the equipment malfunction in 2013, Sterigenics has not experienced an exceedance of any EO emissions limits***. Documents regarding the 2013 incident are available here.

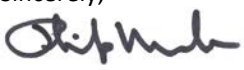
* * *

As the only method approved by the Food and Drug Administration ("FDA") to sterilize millions of critical medical devices, EO sterilization protects individuals needing medical care from life-threatening infection. On an average day, the Willowbrook facility sterilizes 1,000 cardiac devices used in heart surgery, 1,000 knee implants, 1,500 surgical procedure kits, 16,000 catheters, 11,000 syringes for injections used in radiology diagnosis, and thousands of diabetes monitoring and care kits, renal care products, neurosurgical devices, and respiratory care products.

There is no viable alternative for sterilizing these devices. Indeed, for numerous important FDA-approved medical devices, EO sterilization is the only method approved by FDA for ensuring sterility. What many do not understand is that an FDA-required sterilization method for these devices cannot be simply shifted to another technology or another facility. To ensure consistent, reliable removal of pathogens, sterilization processes are validated to a specific technology and, often times, a particular chamber at a specific facility. Accordingly, if the Willowbrook facility were not in operation, ***tens of thousands of patients each day*** would be forced to go without the medical procedures they need. By complying with and going above and beyond what the regulations require, the Willowbrook facility safely uses EO and provides a vital service to patients in Illinois and across the country.

Again, thank you for the opportunity to respond to the gross factual distortions and misleading claims in the "CBS Investigative Report." We would welcome the opportunity to receive you or your staff for a tour of our facility and further discuss any of the responses in this letter. We would be happy to coordinate a time at your convenience.

Sincerely,



Philip Macnabb
President, Sterigenics U.S., LLC